NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BING LI, Individually and on Behalf of All Others Similarly Situated, *Plaintiffs*, v. AETERNA ZENTARIS, INC., DAVID A. DODD, JUERGEN ENGEL, DENNIS TURPIN, JUDE DINGES, RICHARD SACHSE and PAUL BLAKE, *Defendants*.	Civil Action No.: 3:14-cv-7081(PGS)(TJB) **MEMORANDUM AND ORDER**

SHERIDAN, District Judge.

Facts and Procedural History:

This matter is based upon Defendants' Motion to Dismiss the Second Amended Class Action Complaint ("SAC"), which is alleging § 10(b)(5) and 20(a) violations of the federal securities laws. Defendant Aeterna Zentaris, Inc. ("Aeterna") is a biopharmaceutical company engaged in developing treatment in endocrinology and oncology. (SAC ¶ 2.) Plaintiffs purchased Aeterna securities at prices they allege were artificially inflated during the Class Period. The drug in question, AEZS-130, is intended to diagnose adult growth hormone deficiency (AGHD). (Id. ¶ 3.) This action concerns Defendants' effort to obtain FDA approval of a new drug application (NDA) for AEZS-130. Plaintiffs claim that they purchased securities in Aeterna at artificially inflated prices based upon misrepresentations of the drug's likelihood of FDA approval during the Class Period, and have been damaged thereby.

In 2009, Aeterna sought to purchase from Ardana Bioscience ("Ardana"), the rights to the drug AEZS-130. Aeterna performed a due diligence investigation of the data for an incomplete Phase 3 study for an NDA that was pending before the FDA, including a review to check whether each subject in the Ardana study was properly classified. (Id. ¶ 37.) Aeterna then acquired the rights to AEZS-130 on June 8, 2009, when Ardana was experiencing financial problems. (Id. ¶ 36.) The FDA and Aeterna agreed that Aeterna could complete the Phase 3 study begun by Ardana by enrolling additional subjects. (Id. ¶ 5.) On December 20, 2010, the FDA and Aeterna agreed to a Special Protocol Assessment ("SPA"), wherein the design and subject inclusion criteria were set forth for the Phase 3 study. (Id. ¶ 6.) A successful Phase 3 study was essential in order to have the NDA approved by the FDA. (Id. ¶ 7.)

On the same day, December 20, 2010, Aeterna issued a press release stating that Ardana's study included 42 patients with confirmed AGHD, and a control group of 10 subjects without AGHD, which were matched for age, gender, etc. (Id. ¶ 53.) In order to complete the SPA, Aeterna was required to: (1) add 30 normal control subjects; (2) add an additional 20 subjects (10 AGHD and 10 matched normal); and (3) the entire database would include approximately 100 patients (52 from Ardana's portion of the Phase 3 study, and 50 from Aeterna's part.) (Id. ¶ 56.)

Thereafter, Aeterna issued at least one other press release plus some publicly disclosed documents filed with the Securities and Exchange Commission, announcing that it had "favorable top-line results" in completing the Phase 3 study of AEZS-130 in accordance with the SPA parameters. (Id. ¶ 64.) There were other public releases announcing the success of the study leading up to the pre-NDA meeting with the FDA in May 2012.

Aeterna submitted the NDA on November 5, 2013. (Id. ¶ 94.) About a year later, on November 6, 2014, the FDA denied approval of the NDA for AEZS-130, because the Phase 3

trial did not meet its stated primary efficacy objective as agreed to in the SPA. (Id. ¶ 95). According to the SAC, Defendant Dodd revealed that "AEZS-130 was only shown effective when results from two previously-confirmed AGHD patients, who Aeterna later asserted did not have confirmed AGHD, were excluded from the analysis." (Id. ¶ 101). Or, as the Plaintiffs put it, when "two patients were thrown out" of the study. (Id. ¶ 102.) This change in the study group was inconsistent with the requirements of the SPA.

The SAC further alleges that Aeterna's "manipulations" were noted in the Form 20-F that was filed for the year 2011. That Form 20-F states: "Of the 53 AGHD subjects enrolled, 52 received AEZS-130, and 50 who had confirmed AGHD prior to the study entry, were included in this analysis, along with 48 controls." (Id. at ¶ 103). According to the SAC, this means only 50 of the 52 AGHD subjects were included in the analysis. (Id.) Also, one of the 53 AGHD subjects had dropped out before receiving AEZS-130 because of collapsed veins. (Id. n. 7)

The class action is for the period of August 30, 2011 through November 6, 2014 (Id. ¶ 1.) An Amended Complaint was filed in this case on April 10, 2015 (ECF No. 31.) On September 14, 2015, this Court dismissed the Amended Complaint because it failed to demonstrate scienter with the requisite particularity (ECF No. 48.) Plaintiffs were permitted to amend, and they filed the SAC on October 14, 2015 (ECF No. 49.) Defendants now move to dismiss the SAC.

Legal Standard:

On a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), the Court is required to accept as true all allegations in the complaint, and all reasonable inferences that can be drawn therefrom, and to view them in a light most favorable to the non-moving party. *See Oshiver v. Levin*, 38 F.3d 1380, 1384 (3d Cir. 1994). To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true to "state a claim to relief that is plausible

on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also*, *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007). In order to survive a motion to dismiss, the complaint must allege facts that raise the right to relief above the speculative level. *See Twombly*, 550 U.S. at 555. The question is whether the claimant can prove any set of facts consistent with his or her allegations that will entitle him or her to relief, not whether that person will ultimately prevail. *See Semerenko v. Cendant, Corp.*, 223 F.3d 165, 173 (3d Cir. 2000).

To establish a claim under Securities Exchange Act § 10(b) and Rule 10b-5, the plaintiff must satisfy following elements: "(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance…; (5) economic loss; and (6) 'loss causation,' i.e., a causal connection between the material misrepresentation and the loss." *McCabe v. Ernst & Young,* 494 F.3d 418, 424 (3d Cir. 2007).

When applying the elements of the 10(b)(5) claim, the court must invoke the Private Securities Litigation Reform Act ("PSLRA"), wherein the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Institutional Investors Group v. Avaya*, 564 F.3d 242, 253 (3d Cir. 2009). As a result, particularized facts against each defendant are necessary, and courts frown upon group pleading. See, *Israeli v. Team Telecom*, 2006 WL 2883237, *5 (D.N.J. 2006). Generalized imputations of knowledge do not suffice in meeting that burden. *Id.* In looking at a 10-b claim, the complaint must show falsity by specifying allegedly misleading statements, and why the statement was misleading and why it was material. Materiality is "when there is a substantial likelihood that the disclosure of the admitted fact would have been viewed by the reasonable investor as having

significantly altered the 'total mix' of information made available." City of *Roseville Employees' Retirement System v. Horizon Lines, Inc.*, 713 F.Supp.2d 378, 386 (D. Del. 2010).

"Scienter is defined as a mental state embracing intent to deceive, manipulate or defraud," which requires "a knowing or reckless state of mind.'" *Avaya,* 564 F.3d at 252 (internal citations omitted). Usually the inquiry is, "whether all the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegations scrutinized in isolation meets that standard." *Avaya*, 564 F.3d at 267-68. "Cobbling together a litany of inadequate allegations" is insufficient. *Roseville*, 713 F.Supp.2d at 386. A strong inference is more than merely plausible or reasonable, it must be "cogent." *Id.* at 395.

Analysis:

I. Claim against Aeterna

The Court has struggled with applying the scienter standard to this case. Plaintiffs allege that Defendants knew that two of the subjects of the Phase 3 study had to be eliminated to meet the statistical requirements of the study. The SAC does not clearly point to knowledge of any defendant during the Class Period. There are no confidential witnesses attesting to said knowledge, and no memo has been disclosed showing such knowledge. The only time that knowledge can clearly be attributed to Defendants is in November 2013 when the Phase 3 results were submitted to the FDA. At that time, Defendants had to know they were filing for approval based on a modified sample of the SPA by deleting two subjects. This modification warranted disclosure. Even if Aeterna had not believed this modification in the study would have adversely affected its application, the modification warranted some disclosure to investors, especially in light of the prior ongoing positive statements during the approval process. Failing to disclose at that time was reckless.

To be clearer, what is alleged in the SAC that was not set forth in the FAC is that modification of a final dataset after a data lock and a subsequent exclusion of study subjects violates the custom and practice of the industry and FDA. Moreover, it breaches the clinical trial protocol. (SAC ¶¶ 111-113). The FDA's "Statistical Principles for Clinical Trials—E9" states that, according to the "intention to treat" principle, all randomized subjects should be included in the primary analysis of a clinical trial. (Id. ¶ 113). This decreases the possibility of bias. (Id. ¶ 111). Plaintiffs cite to *Corban v. Sarepta Therapeutics, Inc.*, 2015 WL 1505693 (D. Mass. 2015), where the court stated that, "FDA law and regulations recognize that a complete and accurate risk/benefit profile of an investigational product depends upon the data from every subject's experience in the clinical trial…Removal of already collected data—including data from the subjects who have withdrawn from the study—would undermine the scientific and ethic integrity of the research." *Id.* at *2. The existence of these policies suggests that Aeterna was on notice regarding the propriety of their actions during and after the trial, and supports the fact their public announcements were reckless.

As noted above, "scienter is a mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind." *Avaya*, 564 F.3d at 252. Also, the question is "whether all the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegations scrutinized in isolation meets that standard." *Id.* at 267-68. When the facts are all taken together, there are sufficient allegations that Defendants here at least had a "reckless state of mind." Aeterna performed due diligence before taking on the Ardana study, agreed to an SPA with the FDA setting the terms for the study, published press releases after the completion of the study stating that the study was essentially successful and complied with the terms agreed to with the FDA. It is highly improbable that Aeterna had not

known that the data sample was modified in violation of the usual policy. The SAC plausibly establishes that if the Defendants did not have a knowing state of mind, they at least had a reckless state of mind when they did not alert the public to the FDA's concerns before the NDA was rejected.

In regard to the remaining elements of the cause of action, Defendants also assert that Plaintiffs cannot establish false or misleading statements with the required particularity, or sufficiently allege loss causation. This Court finds that Plaintiffs have sufficiently established both of these elements. Aeterna made numerous statements that their trial proved effective in accordance with FDA guidelines when that was not the case. "In the Third Circuit, the making of an affirmative statement on a securities matter triggers a duty to include such information as would prevent the statements from misleading a reasonable investor." *Jaroslawicz v. Engelhartd Corp.*, 704 F. Supp. 1296, 1299 (D.N.J. 1989). "[W]hen a company 'puts an issue into play,' it acquires a duty to disclose information relating to that topic." *In re Merck & Co., Inc. Sec., Derivative & ERISA Litig.*, 2012 WL 3779309 (D.N.J. 2012). At the time of submission, Aeterna knew of the modifications; it should have been disclosed that these patients were not included in contravention to the SPA, and it should been communicated to the investors as well.

Loss causation is another element of the cause of action. Plaintiffs only have to provide "some indication of the loss and the causal connection that the plaintiff has in mind." *Dura Pharms, Inc. v. Broudo*, 544 U.S. 336, 347 (2005). The "issue of loss causation is usually not resolved on a motion to dismiss," because more factual discovery is often necessary. *Dudley v. Haub*, 2013 WL 1845519 at *18 (D.N.J. 2013).

Additionally, Courts have recognized that, "[w]hen someone makes a statement about a security that is misleading but is not yet recognized as such, the security's price will change to

reflect the addition of the misleading statement to the overall mix of publically available information about the security." *Argent Classic Convertible Arbitrage Fund L.P. v. Rite Aid Corp.*, 315 F. Supp. 2d 666, 674 (E.D. Pa. 2004). Indeed, "[b]ecause purchasers rely on the price as an indication of the stock's value, courts presume that purchasers rely indirectly on the misleading statement when they purchase a security in an efficient market at a price that reflects the misleading statement, even if they did not actually and directly rely on the misleading statement when they purchased the security." *Id.* (internal citations omitted). Aeterna's stock had increased following several announcements about the success of its study. Then on November 6, 2014, Aeterna revealed that the FDA had denied its NDA application and that day Aeterna's stock price dropped almost 50% from the prior day's closing. Plaintiffs have successfully pled a claim under 10(b) and Rule 10b-5 against Aeterna.

II. Claims Against Individual Defendants

Plaintiffs make claims against the Individual Defendants, as well. Under Count I, there are allegations under 10(b) and 10b-5 against Defendants Engel, Blake and Pellicione. In Count II, Plaintiffs allege additional violations of § 20(a) against Defendants Engel, Blake, Pellicione, and Dodd. Section 20(a) of the Securities Exchange Act of 1934, 15 U.S.C.A. § 78t(a), "imposes joint and several liability on any person who controls a person liable under any provision of the [Exchange Act]." *In re Exxon Mobil Corp. Sec. Litig.*, 387 F. Supp. 2d 407, 413 (D.N.J. 2005) (internal citations omitted). To maintain a claim under § 20(a), plaintiffs must establish "(1) an underlying violation by the company; and (2) circumstances establishing defendant's control over the company's actions." *Dudley v. Haub*, 2013 WL 1845519, at *20 (D.N.J. 2013). Also, "the overwhelming trend in this circuit" is that "culpable participation does not have to be pled in order to survive a motion to dismiss." *Id.* at *20, n. 5 (internal citations omitted).

Defendant Paul Blake was the Chief Medical Officer of Aeterna from August 5, 2007 to March 13, 2014. The Company's annual reports list him as one of the four senior corporate officers during the Class Period. Allegedly, Blake was responsible for explaining to the FDA Aeterna's reasons for excluding patients, and he attended the pre-NDA meeting. (SAC ¶ 30.) Defendant Nicholas J. Pelliccione was the Company's Senior Vice President, Regulatory Affairs and Quality Assurance from May 2007 through March 2014. The annual reports also listed him as one of the four senior corporate officers of Aeterna during the Class Period. Like Blake, he also purportedly explained Aeterna's position to the FDA, including at the pre-NDA meeting. (SAC ¶ 31.) The allegations in the SAC indicate that both Blake and Pelliccione were intimately involved in the study, and in discussions with the FDA. Under § 20(b), the allegations do "support a reasonable inference that [defendants] had the potential to influence and direct the activities of the primary violator'." *In re Loewen Group Inc.*, 2004 WL 1853137, at *26 (E.D. Pa. 2004). However, there are not enough facts showing that they actually made misrepresentations to the public. Therefore, the § 20(b) claim against Blake and Pelliccione may proceed, while the § 10(b) claim against them is dismissed.

Defendant David A. Dodd joined Aeterna as CEO in April 2013 (SAC ¶ 29). Dodd was involved in the completion of the NDA submission, said that he believed Aeterna was addressing the FDA's concerns, and he announced that the FDA had rejected their submission. It is not clear that he made any misrepresentations, but he does satisfy the 20(a) standard. The 20(a) claim will remain against Dodd.

Finally, Defendant Juergen Engel served as the Company's President and CEO from September 2008 to April 2013. He allegedly attended the pre-NDA meeting, and he also stated in an August 30, 2011 press release that AEZS-130 had met the SPA's parameters and

demonstrated effectiveness. He signed each 20-F Form during the Class Period. The SAC suggests that he was aware of his Company's actions since the purchase of Ardana, and the timing of his departure—about six months before submission of the clinical testing results—gives rise to a plausible inference that he knew something about the clinical modifications. (SAC ¶ 28.) Neither claim against Engel will be dismissed.

There is also a dispute as to the proper service of process on Defendants Engel, Blake and Pelliccione. Plaintiffs claim that their server affixed a copy of the SAC and summons to Pelliccione's residence in New York, and copies were mailed to him on November 12, 2015. This was apparently done after the server attempted but failed to serve him at his residence on three separate occasions. (See Exhibit 1 to the Declaration of Laurence Rosen ("Rosen Decl.")). This is permitted under New York Civil Practice Law and Rules ("CPLR") in this circumstance. See CPLR 308. Plaintiffs state that they initiated service on Engel and Blake through the Hague Convention, since they reside in Germany and the U.K., respectively. The time period required by Rule 4(m) for service does not apply to foreign defendants residing outside of the U.S. See Fed. R. Civ. P. 4(m). The Court is satisfied with the process here.

Finally, there are no allegations in the SAC implicating named Defendants Dennis Turpin, Jude Dinges, or Dennis Sachse. Therefore, they are all dismissed.

ORDER

Having carefully reviewed and taken into consideration the submissions of the parties, as well as the arguments and exhibits therein presented, for the reasons stated on the record, and for good cause shown,

IT IS on this 2nd day of March, 2016,

ORDERED that Defendants' Motion to Dismiss Plaintiffs' Second Amended Complaint [ECF No. 57] is DENIED in part and GRANTED in part; and it is further

ORDERED that the Motion to Dismiss Count I is DENIED as to Aeterna and Engel; and it is GRANTED as to Blake, and Pelliccione; and it is further

ORDERED that the Motion to Dismiss Count II is DENIED as to Engel, Dodd, Blake, and Pelliccione; and it is further

ORDERED that Turpin, Dinges, and Sachse are dismissed from this action.

PETER G. SHERIDAN, U.S.D.J.